

REMARKS:

The claims in the application are now 21-48.

Favorable reconsideration of the application as amended is respectfully requested.

The set of claims presented herein eliminates the double patenting issue raised on page 4 of the Office Action. In this regard, Claims 21-48 presented herein find clear support throughout the present application and figures. More particularly, independent Claim 21 is directed to the recitation found in original Claim 1 and additionally reciting the sericin/hydrolyzed product in an effective amount to prevent colon cancer (Test Example 7 at pages 18-19 of the present application) and the sericin being water-soluble (Page 8, line 2 of the present application). Claim 22 finds support in the first paragraph on page 5 of the specification while Claim 23 finds support at page 7, lines 13-23 of the specification and Claim 24 finds support at the bottom of page 17 of the specification in Test Example 6. Additionally, Claim 25 finds support in the first paragraph on page 20 of the specification, with Claims 26 and 27 respectively corresponding to recitation found in original Claims 2 and 3.

Support for Claim 28 can be found in Examples 1 and 2 on page 9 of the specification, while support for Claim 29 can be found at page 8, line 24 of the specification. Claim 30 corresponds to recitation found in original Claim 7 while Claim 31 corresponds to original Claim 6 rewritten into independent form and additionally reciting the sericin is water-soluble, as recited in independent Claim 21 supra. Support for Claim 32 can be found at page 7, lines 13-23 of the specification

while Claims 33 and 34 respectively correspond to recitation presented in Claims 28 and 29 supra. Claim 35 finds support, e.g., in Table 1 on page 13 of the present application, while Claim 36 is directed to similar recitation as in Claims 22-25 supra. Claim 37 also corresponds to recitation found in original Claim 7 while support for Claims 38 and 39 can be found in the comparative testing outlined in Test Examples 1-7 at pages 9-20 of the present application and illustrated in Figs. 1-4.

Independent Claim 40 is directed to a method of preventing colon cancer and containing analogous recitation to independent Claim 21 supra while Claim 41 contains analogous recitation to Claim 29 supra and Claim 42 analogous recitation to Claim 28 supra. Claim 43 contains analogous recitation to Claims 22-25 supra while Claim 44 is directed to recitation found in original Claims 2 and 3. Claim 45 is directed to recitation found in original Claim 7 with Claims 46-48 directed to analogous recitation found in Claims 32, 35 and 38 respectively.

Claims 1-5, 7-9, 11-15 and 18-20 have been rejected under 35 U.S.C. § 102 as being anticipated by JP-256351 or U.S. Pat. No. 6,165,982 to Yamada et al., while Claims 6, 10, 16 and 17 have been rejected under 35 U.S.C. §103 as obvious additionally in view of either the Vargas or Alberts et al. citations. However, it is respectfully submitted the invention recited in all pending claims herein is patentable over the applied art, for the following reasons.

The present invention is explicitly directed to providing a preparation for preventing colon cancer (and providing other gastrointestinal benefits) by administering an effective amount of water-soluble sericin or hydrolyzed product thereof. These benefits provided by the claimed invention have been explicitly

documented in the demonstrative and comparative testing set forth in Test Examples 1-7 on pages 9-20 of the present application and illustrated, e.g., in accompanying Figs. 1-4. In this regard, the claims, notably preparation Claims 21-39, have been phrased to give patentable weight to the claimed effective amounts, in accordance with the comments at the top of page 4 of the Office Action.

Yamada et al have been assigned to the same assignee, Seiren Co., Ltd., as the present application (please see the cover page of Yamada et al); the assignment to Seiren Co., Ltd. of the present application was recorded with the Patent and Trademark Office on August 31, 2001 at Reel 012293, Frame 0269. Accordingly, the rejection under 35 U.S.C. §§ 102(e)/103 over Yamada et al in view of the subordinate citations, has been eliminated in accordance with M.P.E.P. §§ 706.02(l)(1) and (2). Therefore, at the very least, the obviousness rejection over Yamada et al. has been eliminated regarding Claims 31-38 presented herein.

The right to consider and if deemed necessary, prepare and file a Declaration under 37 C.F.R. §§ 1.131 or 1.132 to address the disclosure found in Yamada et al. concerning the anticipatory rejection in accordance with M.P.E.P. § 715.01(a), is explicitly reserved by the Applicants. However, it is respectfully submitted Yamada et al. fail to anticipate the invention recited in any claim herein, for the following reasons.

Yamada et al are explicitly directed to inhibiting tyrosinase activity; treatment of the gastrointestinal ailments by the claimed invention herein is not disclosed in Yamada et al. By the same token, JP1-256351 is directed to producing food extremely soft and pleasant to the palate by adding drink to an aqueous

solution of silk fibroin and sericin and then gelling the fibroin and sericin by adjusting pH to gel the fibroin and sericin. Accordingly, JP1-256351 also fails to disclose treatment of gastrointestinal ailments in the manner of the claimed invention.

Moreover, JP1-256351 clearly teaches a food which comprises a gelled silk fibroin and/or sericin and a beverage, whereas the sericins used in the claimed invention are water-soluble and not gels. Accordingly, JP1-256351 and Yamada et al fail to anticipate the invention recited in any claim pending herein.

Concerning the obviousness rejection, Vargas simply reports administering a particularly daily dose of calcium significantly decreases DNA-synthesizing cells of high-risk patients, with several clinical trials still underway, while Alberts et al. conclude neither wheat bran fiber nor calcium carbonate has significant effect on cell proliferation rates in the colorectal cancer study reported therein. Firstly, these two references disclose studies with calcium alone, i.e., not with a mineral mix as recited in Claims 31-38. Secondly, there is no suggestion in Vargas and/or Alberts et al., even if combined with JP1-256351, that water-soluble sericin improves intestinal absorption of a mineral mix.

Thirdly, Alberts et al actually disclose the results with their calcium supplement to be ineffective. It is well-settled teachings of a reference must be considered in their entirety. Accordingly, even if one skilled in the art combined the teachings of JP1-256351 with Alberts et al., then such a combined teaching would actually lead away from practicing the invention as recited, e.g., in Claims 31-38.

The remaining art of record has not been applied against the claims and will not be commented upon further at this time.

Accordingly, in view of the forgoing amendment and accompanying remarks, it is respectfully submitted all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions. A petition for an automatic one month extension of time for response under 37 C.F.R. § 1.136(a) is enclosed in triplicate together with the requisite petition fee plus the fee for the additional claims introduced herein.

Early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "George M. Kaplan", is written over a horizontal line.

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